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Dkt.#627-A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : BAKHUTASHVILI, Vladimir
U.S. Serial No.: 09/928,178, claiming benefit of U.S.
Serial No. 60/224,112, filed August 9,
2000
Filed : August 9, 2001
FOR : AMNIOTIC APOPTOSIS MODULATING SUBSTANCES

141-07 20th Ave., Suite 604
Whitestone, New York 11357

January 29, 2002

Honorable Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R.
§1.56, Applicant would like to direct the Examiner's attention
to the following references which are listed on Form PTO-1449
(Exhibit A) and are attached hereto as Exhibits 1 through 59,
respectively:

1. Bakhutashvili A, Chikovani T, Bakhutashvili V, Imedidze
E. Immunopharmacology of preparation Plaferon-LB. Intern
J Immunorehab 1994; 1 (S): 44. (Abstract) [Exhibit 1]
2. Bakhutashvili A, Cheishvili N, Chikovani T, Bakhutashvili
V. Plaferon LB - a new immunodilatory drug. Abstracts XVI
European Congress of Allergology and Clinical Immunology,
Madrid, Spain, 25-30 June 1995. Europ J Allergy Clin
Immunol 1995; 50(26): 9. Abstract # OC-009. (Abstract)
[Exhibit 2]
3. Bakhutashvili A, Jaguzhinsky L, Bakhutashvili I,
Kadagidze Z, et al. Amnion apoptosis modulator. Int J
Immunorehab 2001, 3(2): 17-22. [Exhibit 3]

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4. Bakhutashvili V, Bakhutashvili A, Chikovani T, Cheishvili N. Immunomodulatory activity of Plaferon-LB. Georg Symp Project Development and Conversion; Collection of Reports 1995; 189-191. [Exhibit 4]
5. Bakhutashvili V, Chikovani T, Rukhadze R. The perspectives of a new immunomodulator Plaferon LB in endocrinologic practice. Proceedings of Tbilisi State Medical University 1996; 32: 21-23. [Exhibit 5]
6. Bakhutashvili V, Malashkhia V, Mikeladze D, Chikhladze M, Malashkhia Y, Bakhutashvili A. Effect of Plaferon-LB during treatment of medicamentously resistant form of epilepsy. Int. J Immunorehab 1996; 3: 28-37. [Exhibit 6]
7. Bakhutashvili V, Javakhishvili N, Tsagareli Z, Kipshidze N. Cardioprotective effects of Plaferon LB in a canine model. The J Heart Failure 1997 May; 4(1): 38. Abstract #151. (Abstract) [Exhibit 7]
8. Bakhutashvili V, Gagua M, Garishvili T, Gelashvili L, Kharebava G, Kvaratskhelia E, Menteshashvili A. Human placenta antioxidant compounds of peptide nature. 11th International Symposium on Atherosclerosis, Paris 1997 October 5-9, Int J Res Invest on Atherosclerosis and Related Diseases October 1997; 134(1-2): 199. Poster # 3.P.4. (Abstract) [Exhibit 8]
9. Bakhutashvili V, Chikovani T, Bakhutashvili I, Cheishvili N, Kukuladze N, Bakhutashvili A. Some pharmacological characteristics of Immunomodulator Plaferon-LB. 10th International Congress of Immunology in New Delhi, 1998 Nov 1-6; The Immunologist 1998 Suppl 1: 586. (Abstract). [Exhibit 9]

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10. Bakhutashvili V, Shakarishvili R, Geladze T, Tatishvili N, Bakhutashvili A, Cheishvili N, Chikovani T, Sobera LA. "Plaferon," Drugs of the Future 1999; 24(9): 974-977. [Exhibit 10]
11. Bakhutashvili V, Telia D, Katsarava V. Use of Plaferon-LB and cromoglycate in patients with symptomatic asthma. Int J Immunorehab 1999; 11: 214-215. [Exhibit 11]
12. Bakhutashvili V, Pagava K, Telia A, Jorjoladze N, Kokaia L, Alavidze M, Kvachadze L. Bronchotropic effect of Plaferon-LB. Int J Immunorehabilitation 1999; 5: 51-53. [Exhibit 12]
13. Bakhutashvili V, Chikovani T, Bakhutashvili A, Dolidze T, Nanava N, Kvitaishvili G. Dynamics of some immunological indices in case of Plaferon-LB therapy. Europ. J. Allergy and Clin Immun 1999; 54(52 S): 77. Abstract # P37.. (Abstract) [Exhibit 13]
14. Bakhutashvili V, Chikovani T, Bochorishvili T, Metreveli D, Pavliashvili D. Results of treatment of acute B hepatitis by Plaferon LB. Bulletin of Georgian Academy of Science, Biology Series 1999 25 (1-3):21-23. [Exhibit 14]
15. Bakhutashvili V, Bakradze I, Aladashvili A. Impact of perioperational immunotherapy upon nonspecific resistance and specific immune status in patients with bowel cancer and upon frequency and spectrum of complications in nearest postoperative period. Int J Immunorehab 2000;2 (2): 4. Abstract # 3. (Abstract) [Exhibit 15]
16. Beridze M. Effect of Plaferon-LB on several clinical and neuroimmunological indices. Georgian Medical News 1998; 6(39): 27-30. [Exhibit 16]

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17. Beridze M, Malashkhia V, Bakhutashvili V. Neuroprotective action of immunomodulator Plaferon-LB. Int J of Immunorehab 1999; 14: 114. Abstract # 15. (Abstract)
[Exhibit 17]

18. Havadagiani G, Chavchanidze D, Kalmahelidze V, Sulhanishvili V, Stepina J, Bakhutashvili V, Managadze L. Protective effect of Plaferon LB preparation on acute ischemic renal injury in experiments. Archivum Urologium Belgrade 1989; 30: 45-51. **[Exhibit 18]**

19. Chavchanidze D, Sanikidze T, Sulkanishvili V, Bakhutashvili V, Managadze L. Changes of blood paramagnetic centers under the influence of shock waves on kidneys and membrane-protector effect of Plaferon-LB in experiment. Bulletin of the Georgian Academy of Sciences 1998; 158(2): 332-335. **[Exhibit 19]**

20. Chavchanidze D, Sanikidze T, Bakhutashvili V, Managadze L. Determination of traumatic influence of shock waves and membrane-protecting effects of Plaferon-LB on the renal parenchyma during extracorporeal lithotripsy in experiment. Proc Georgian Acad Sci; Biol Ser 1998; 24(1-6): 53-59. **[Exhibit 20]**

21. Cheishvili N, Kukuladze N, Bakhutashvili A, Bakhutashvili V. Effect of Plaferon-LB on proliferative activity of human periferal blood mononuclear cells and murine splenocytes. Reports of Georgian Academy of Science 1994; 150 (1): 142-143. **[Exhibit 21]**

22. Chikovani T, Cheishvili N, Bakhutashvili A, Bakhutashvili V. The influence of Plaferon LB on synthesis of

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interleukins. Int J Immunorehab 1996; 3: 96. (Abstract)
[Exhibit 22]

23. Chikovani T, Cheishvili N, Pirtskalava T, Pantsulaia I, Bakhutashvili V. Plaferon LB as a blocker of neurotoxic effect of glutamate. Int. J Immunorehab 1997; 5: 46. (Abstract) [Exhibit 23]

24. Chikovani T, Cheishvili N, Pantsulaia I, Bakhutashvili V. Immunopotential activity of Plaferon LB fractions. Int J Immunorehab 1998; (9): 5. (Abstract) [Exhibit 24]

25. Chikovani T, Pavliashvili D, Bakhutashvili V. Different ways of therapy by Plaferon LB in patients with acute B viral hepatitis. Abstracts of International Falk Workshop, New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 52. (Abstract) [Exhibit 25]

26. Chikovani T, Cheishvili N, Pantsulaia I, Bakhutashvili V, Bakhutashvili A. Immunologic study of human placental factor. Eur J Allergy Clin Immun; 1999; 54 (52 S): 89. Abstract # P81. (Abstract) [Exhibit 26]

27. Chikovani T, Rukhadze R, Bakhutashvili V, Sanikidze T, Pantsulaia I. Antioxidant action of immunomodulatory drug Plaferon LB in experimental thyroid pathology. Int J Immunorehab 1999; 12(S): 14-18. [Exhibit 27]

28. Dolidze Z, Gelovani M, Bakhutashvili V, Chikovani T. Plaferon antirecidive action on the children with idiopathic nephrotic syndrome. Bull Acad Sci Geo 1992; 145 (1): 209-11. [Exhibit 28]

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29. Gagua M, Russia L, Kupatadze R, Simonidze M, Bakhutashvili V. Investigation of polipeptide contents of Plaferon LB. Bulletin of Acad of Sci of Georgia 1996; 3(153): 450-452. [Exhibit 29]
30. Gagua M, Dzidziguri D, Bakhutashvili V. Influence of Plaferon LB on the / transcriptional activity of regenerating liver and kidney cells. International-European A.I.R.R. Conference; Tbilisi, 1999 October 4-9; Collection of reports: 11. (Abstract) [Exhibit 30]
31. Gagua M, Dzidziguri D, Mikadze E, Rukhadze M, Bakhutashvili I, Bakhutashvili V. Effect of Plaferon LB on morpho-functional activity of hepatocytes under conditions of hormonal disbalance in white rats. Bulletin of Georgian Acad of Sci 1999; 160 (3): 574-576. [Exhibit 31]
32. Gurgenidze G, Chogovadze M, Bakhutashvili V. Plaferon-induced in vitro inhibition of mitogen-activated T-lymphocyte proliferation in steroid-resistant asthmatic patients. Trans-Caucasian J Immunology 1999; 1 (2): 12-19. [Exhibit 32]
33. Johnson DW, Kipshidze N, Javahishvili N, Zagareli Z, Bakhutashvili V. Cardioprotective effects of Plaferon-LB in canine model. First International Congress on Heart Disease-New Trends in Research, Diagnosis and Treatment; Washington DC, USA; 1999 May 16-19; Book of Abstracts: 46. Abstract # 30. (Abstract) [Exhibit 33]
34. Macharadze D, Bakhutashvili V, Fedotova E. Plaferon-LB in immuno-rehabilitation of children with bronchial asthma. Int J Immunorehab 1998; 8: 67. Abstract # 249. (Abstract) [Exhibit 34]

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Filed : August 9, 2001
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35. Maisuradze E, Garishvili T, Bakhutashvili V. Inhibition of Bee Venom Phospholipase A2 activity by Plaferon LB. Bulletin of the Georgian Academy of Sciences 1998; 157, (2): 317-319. **[Exhibit 35]**
36. Beridze M, Malashkhia N, Bakhutashvili V. Immunomodulator Plaferon Lb in the treatment of acute ischemic stroke. Int J Immunorehab 1999; 12: 161-165. **[Exhibit 36]**
37. Metreveli D, Bakhutashvili V, Bochorishvili T, Jamutashvili M, Gingolava M. Influence of Plaferon-LB on clinical course of Hepatitis and Laboratory Data in Children. International Falk Workshop - New Aspects in Hepatology and Gastroenterology; May 29-30, 1998; Tbilisi, Georgia. Abstract # 195. (Abstract) **[Exhibit 37]**
38. Metreveli D, Bakhutashvili A, Chikovani T, Pavliashvili D, Bakhutashvili V. Long term results of treatment of B hepatitis with Plaferon LB. Int J Immunorehab 1999; 12: 43. Abstract # 169. (Abstract) **[Exhibit 38]**
39. Mikeladze D, Djanashia N, Djanashvili C, Bakhutashvili V. Influence of Plaferon upon main excitatory and inhibitory neurotransmitters of brain. Tbilisi 1995; 332-337. **[Exhibit 39]**
40. Nadareishvili Z, Malashkhia Y, Bakhutashvili V. Plaferon in the treatment of herpes zoster ganglioneuritis in intravenous drug users. Int Conf AIDS, Berlin 1993, June 6-11; 9 (1): 344. Abstract # PO-B08-1254. (Abstract) **[Exhibit 40]**
41. Pantsulaia I, Chikovani T, Ruhadze R, Sanikidze T, Bakhutashvili V. Influence Plaferon-LB on changes in organs of immune system in case of experimental acute

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hyperthyroidism. Proceedings of the 4th Republic Scientific Practical Conference, Kutaisi, 1998 May 31; Collection of reports: 24. (Abstract) **[Exhibit 41]**

42. Pantsulaia I, Chikovani T, Cheishvili N, Garishvili T, Kharebava G, Bakhutashvili V, Zhgenti M. Alteration of lymphocytes' proliferative activity in vitro under the influence of plaferon LB fractions. Proc Georgian Acad Sci, Biology Series 1999; 25 (1-6): 75-77. **[Exhibit 42]**

43. Pantsulaia I, Cheishvili N, Kukuladze N, Jgenti M, Chikovani T. Influence of PlaferonLB on proliferative activity of splenocytes in experimental hyper- and hypothyroidism. Int J Immunorehab 2000; 2 (2): 49. Abstract # 157. (Abstract) **[Exhibit 43]**

44. Pantsulaia I, Pkhakadze E, Cheishvili N, Chikovani T, Jgenti M. Influence of Plaferon LB on the course of moderate periodontitis. Int J Immunorehabilitation 2000; 2 (2): 89. Abstract # 294. (Abstract) **[Exhibit 44]**

45. Pavliashvili D, Chikovani T, Metreveli D, Sanikidze T, Bakhutashvili V. The effect of sublingual administration of Plaferon LB on metabolic disorders during viral hepatitis B. Georgian Med News 1999; 9 (54): 65-67. **[Exhibit 45]**

46. Rukhadze R, Sanikidze T, Bakhutashvili V, Chikovani T, Pantsulaia I, Jgenti M. Influence of plaferon LB on metabolic disorders in liver during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 333-337. **[Exhibit 46]**

47. Rukhadze R, Sanikidze T, Bakhutashvili V, Chikovani T, Nikoleishvili L, Pantsulaia I, Jgenti M. An interim

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report on the effect of Plaferon LB on metabolic changes in myocardium during experimental hyperthyroidism. Proc Georgian Acad Sci, Biol Ser 1998; 24 (1-6): 339-343.

[Exhibit 47]

48. Rukhadze R, Sanikidze T, Cigovani T, Bakhutashvili V. Influence of Plaferon LB on some indices of liver mitochondria during experimental hyperthyroidism. Georgian Medical News 1999; 2: 7-9. [Exhibit 48]
49. Rukhadze R, Chikovani T, Bakhutashvili V, Sanikidze T, Metreveli D, Pantsulaia I, Balarjishvili M. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of Thyrotoxicosis. Bulletin of Georgian Academy of Science 1999; 160 (3): 580-582. [Exhibit 49]
50. Rukhadze R, Chikovani T, Pantsulaia I, Bakhutashvili V. The influence of Plaferon-LB on some splenic morphometric indices during experimental hyper- and hypothyroidism. Int J Immunorehab 1999; 14: 117. Abstract # 76. (Abstract) [Exhibit 50]
51. Rukhadze R, Chikovani T, Bakhutashvili V, Sanikidze T, Metreveli D, Pantsulaia I, Balarjishvili M. Influence of Plaferon LB on the metabolism of nitric oxide (NO) in case of hypothyroidism. Bulletin of Georgian Academy of Science; 2000, 161 (1): 156-158. [Exhibit 51]
52. Ryazantseva S, Vysotskaja I, Ermilova V, Bakhutashvili V. Immunomorphological changes in breast cancer as a result of preoperative administration of immunomodulator Plaferon. Herald of Oncology National Center, Russian Academy of Science; Clinical Investigations 1999; 4: 37. [Exhibit 52]

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Filed : August 9, 2001
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53. Shakarishvili R, Sanikidze T, Mitagvaria N, Beridze M, Mikeladze D, Bakhutashvili V. The role of oxygen and nitrogen reactive species in pathogenesis of ischemic stroke. Report on Scientific Session of NATO, Tbilisi, Georgia, October 2001. In press. [Exhibit 53]
54. Tatishvili N, Bakhutashvili V, Simonia G. Local use of Plaferon LB in rheumathology. Int J Immunorehab 1999; 12: 81. Abstract # 303. (Abstract) [Exhibit 54]
55. Telia A, Bakhutashvili V, Jorjoladze N, Kvachadze L. Use of Plaferon LB in children with bronchial asthma. Int J Immunorehab 1997; 7: 139. (Abstract) [Exhibit 55]
56. Telia A, Bakhutashvili V, Kokaia L, Jorjoladze N, Kvachadze L, Alavidze M. Preventive effect of Plaferon LB on hystamine-induced bronchoconstriction obstruction in guinea pig. Int J Immunorehab 1998; 9: 28. (Abstract) [Exhibit 56]
57. Telia A, Bakhutashvili V, Kokaia L, Alavidze M, Pagava K, Jorjoladze N, Kvachadze L. Plaferon LB as an alternative preparation for treatment of bronchial asthma in children. Int J Immunorehab 1998; 10: 165-167. [Exhibit 57]
58. Telia A, Katsarava V, Bakhutashvili V. Impact of Plaferon LB on bronchial and alveolar cell count and ventilatory function in patients with asthma. Int J Immunorehab 1999; 12 (S): 24. [Exhibit 58]
59. Telia A, Katsarava V, Bakhutashvili V. Influence of Plaferon LB on Proportion of Bal cells and Ventilatory Function in Patients with Asthma. Int J Immunorehab 1999; 12: 164-165. [Exhibit 59]

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If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan

Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant
141-07 20th Ave., Suite 604
Whitestone, New York 11357
Tel: (718) 357-8836
Fax: (718) 357-8552

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
<u>Albert Wai-Kit Chan</u>	<u>1/29/02</u>
Albert Wai-Kit Chan	Date
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